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No. 134

IN THE

Supreme Court of the United States

October Term, 1948

RESEARCH LABORATORIES, INC.,
Petitioner,

v.

UNITED STATES OF AMERICA

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES CIRCUIT COURT OF APPEALS FOR THE NINTH CIRCUIT

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UNITED STATES OF AMERICA

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES CIRCUIT COURT OF APPEALS FOR THE NINTH CIRCUIT

Your petitioner, Research Laboratories, Inc., respectfully prays that a writ of certiorari issue to review the decree of the United States Circuit Court of Appeals for the Ninth Circuit, entered herein on April 2, 1948, affirming the judgments of the District Court of the United States for the Western District of Washington, Southern Division.

Opinion Below

The opinion of the Circuit Court of Appeals (R. 1102-1134) is reported in 167 F. 2d 410. The District Court wrote no opinion.

Jurisdiction

The decree of the Circuit Court of Appeals was entered on April 2, 1948 (R. 1135). On April 29, 1948, it stayed its mandate pending application to this Court for a writ of certiorari. The jurisdiction of this Court is invoked under Section 240(a) of the Judicial Code, as amended by the Act of February 13, 1925.

Question Presented

Whether, in a libel proceeding involving an allegation of false and misleading labeling concerning the effectiveness of a drug product in violation of the Federal Food, Drug, and Cosmetic Act, it is proper to submit the case to the jury when the evidence shows that there is an honest difference of medical opinion concerning the article's effectiveness.

Statute Involved

The pertinent provisions of the Federal Food, Drug, and Cosmetic Act (52 Stat. 1040, as amended, 21 U. S. C. 301 et seq.) are set out in the Appendix.

Statement

Petitioner is a corporation engaged in the manufacture, sale and distribution of a proprietary drug product known as "Nue-Ovo". Respondent filed four libel actions involving the article in three different federal district courts pursuant to Section 304(a) of the Federal Food, Drug, and Cosmetic Act (R. 2, 56, 78, 92). Each alleged that the article's labeling was "false and misleading" within the meaning of Section 502(a) of the Act (21 U. S. C. 352(a)), in that the labeling represented the article as effective in the treatment of arthritis, rheumatism, neuritis, sciatica and lumbago, whereas, it was alleged, the article is not effective in the treatment of those conditions (R. 4, 58, 80, 94). In accordance with Section 304(b) of the Act (21 U. S. C. 334

(b)), all of the cases were removed to and consolidated for trial in the District Court of the United States for the Western District of Washington, Southern Division (R. 17).

Following pre-trial conferences, the district court entered a pre-trial order (R. 20-29) stating that the agreed issues were (R. 22-23, 646-647): (1) whether the labeling suggests that the article is effective in the treatment of arthritis, rheumatism, neuritis, sciatica or lumbago; (2) whether the article is ineffective in the treatment of those conditions; and (3) whether the article is therefore misbranded. There was no issue of harmfulness in the cases (R. 23). Petitioner later admitted that the labeling represented the product to be effective (R. 1068, 1105), so that the only real issue was whether the product is effective.

At the trial before a jury, petitioner presented 27 lay witnesses[1] and 5 medical experts, all of whom testified that the product is effective. The medical testimony in support of the product may be briefly summarized as follows:[2]

(1) Dr. Ira. A. Manville, a practitioner for 23 years and Associate Professor of Medicine at Oregon State University (R. 800), testified that he had conducted clinical tests with the article from 1939 to 1942 (R. 801-802). He concluded that 65% of the patients were definitely benefited (R. 802-807, 813-823, 826-828). Also, he has used it on his own private patients with good results (R. 809).

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[1] See R. 629, 677, 680-681, 685-686, 692, 698, 703-705, 712, 715, 718-719, 724, 728, 798, 895, 899-900, 912-913, 917-918, 922, 927, 932-933, 938, 942, 946, 948-949, 953-954, 958, 962-963.

[2] A considerable part of petitioner's medical testimony related to Sal-Trag rather than Nue-Ovo. Sal-Trag is simply a concentrated form of Nue-Ovo prepared for sale to licensed physicians, whereas Nue-Ovo is sold to consumers (R. 781-783). The trial court instructed the jury that if it found the two to be the same, it should consider the Sal-Trag evidence as applicable to Nue-Ovo (R. 1065). The uncontradicted evidence was that they are identical (R. 781-783, 747-748, 786, 801). The trial court obviously was satisfied in this regard, for in the earlier stages of the trial it ruled that unless the identicalness were shown the Sal-Trag evidence would be excluded (R. 736, 777), and after introduction of the evidence above referred to it overruled respondent's objection to such evidence (R. 803). The Circuit Court of Appeals was also satisfied that the two articles are the same (R. 1103). It is apparent therefore that the testimony on both articles is entitled to the same weight.

(2) Dr. G. M. Taylor, a practitioner for 22 years, senior orthopedic doctor at Los Angeles General Hospital and acting head of the Department of Orthopedic Surgery at the College of Medical Evangelists, a grade-A medical school (R. 967-968), testified that he had conducted clinical tests with the article for a period of 3 years (R. 969-970, 974). Alternating over 100 patients, he used a vaccine treatment in general use at the time on one and the article in question on another, and found that the product was effective in from 78 to 88% of the cases, as compared with from 46 to 59% in the case of the vaccine (R. 970-973). He has also used the article in private practice with beneficial results (R. 973-974).

(3) Dr. Carl E. Lund, a practitioner for 10½ years, Vice-President of St. Joseph's Hospital in Burbank, California and on the staffs of several other hospitals (R. 993-994), testified that he had used the article on his patients for over 9 years with good results (R. 994-996). In his own practice, he used laboratory tests to determine whether the article brought any real improvement, rather than relying on the statements of patients (R. 996-997). He concluded that the article was effective in from 85 to 90% of the cases (R. 998-1004).

(4) Dr. Daniel E. Snell, a Doctor of Osteopathy in practice for 24 years (R. 776, 884), testified that he had used the product with his patients for 11 years with beneficial results in about 75% of the cases (R. 878-883). Also, he had taken the product himself with similar effectiveness (R. 874-877).

(5) Dr. Wendell White, a practicing physician for 34 years (R. 732), testified that he had used the article effectively with his patients for 8 years (R. 736, 740-742, 744-745). Likewise, he took it himself with good results (R. 738-739).

The evidence also showed that in the Los Angeles area alone approximately 1219 doctors have used the product, and 237 of them have used it consistently and in quantity for a period of from 2 to 12 years (R. 633-634).

Respondent presented 7 lay users who testified that the product had been ineffective in their cases, and 8 doctors who gave their opinions on the question of effectiveness. This medical testimony may be summarized as follows:

(1) Three doctors testified that they had made studies with the product, in the sense that they had given it to a limited group of patients over a short period of time. One gave it to six patients for 60 days and conducted laboratory tests on the patients, after which she concluded that five did not improve and one felt better (R. 351-353). Another administered the article to six patients for six weeks, made no laboratory tests, and testified that five patients felt no improvement while one did (R. 267-269). The third gave the product to seven patients for 60 days while conducting simultaneous laboratory tests on them, and reported no improvement in any of the patients (R. 399-400). All of these three doctors testified that on the basis of their limited tests it was their *opinion* that the product was not effective (R. 356-359, 272, 274, 276, 404)[3].

(2) Two doctors who had never used or prescribed the product went through the list of ingredients one by one and testified that in their *opinion* each of the ingredients would be ineffective (R. 193-202, 225-227). Both also testified that ingredients which are individually ineffective do not become effective by combination (R. 202-203, 230-231)[4].

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[3] Each of these three doctors also testified as to opinions formed on the basis of earlier tests made with a product sold under the same name but having different ingredients (R. 353, 270, 401).

[4] In contrast with this testimony, three of petitioner's medical experts testified that individually ineffective ingredients often become effective through combination (R. 771, 774, 810-811, 1012).

(3) Three doctors who have never had any experience with the product testified, simply on the basis of a reading of the article's ingredients and quantitative analysis, that in their *opinion* the product would not be effective (R. 486-488, 560-562, 579-581).

At the close of the evidence, petitioner moved for a directed verdict in each case (R. 1045-1046), and later to set aside the verdicts and judgments for respondent (R. 38), on the ground that the evidence showed only a difference of opinion between qualified physicians as to the effectiveness of the article. The motions were denied (R. 1050, 45, 75, 90, 103), and petitioner appealed to the Circuit Court of Appeals (R. 46, 76, 91, 104). The judgments of the district court were stayed pending appeal (R. 34, 70, 85, 99).

On April 2, 1948, the Circuit Court of Appeals rendered an opinion affirming the judgments of the district court (R. 1102-1134). It recognized that this Court had established in three cases [5] that there should be a directed verdict against the Government when the evidence shows an honest difference of opinion concerning the effectiveness of a product. It concluded, however, that the rule of this Court had been limited by several later lower federal court decisions. It held that respondent's expert testimony concerning tests made with the product, as to the consensus of medical opinion regarding the value of its individual ingredients, and their personal opinions even in the absence of any experience with the product, was "ample evidence to support the verdict of the jury" (R. 1117-1118). It did not mention petitioner's expert testimony and did not once discuss the question of whether the evidence as a whole showed an honest difference of opinion. Ap-

[5] *School of Magnetic Healing v. McAnnulty*, 187 U. S. 94; *United States v. Johnson*, 221 U. S. 488; *Seven Cases v. United States*, 239 U. S. 510.

parently, it reasoned that respondent's evidence was factual and not opinion evidence, that the question of effectiveness thus became one of fact, and that therefore it was a question for the jury no matter what the difference of opinion.

Specification of Errors to be Urged

The Circuit Court of Appeals erred:

(1) In holding that it was proper to submit the case to the jury even though the evidence showed that there was an honest difference of medical opinion concerning the article's effectiveness.

(2) In holding that respondent's evidence was factual, and that therefore it was proper to submit the case to the jury, despite the great amount of testimony of qualified experts that the article is effective.

(3) In affirming the judgments of the district court.

Reasons for Granting the Writ

1. The Circuit Court of Appeals has decided a federal question in a way in conflict with applicable decisions of this Court.

In *School of Magnetic Healing v. McAnnulty*, 187 U. S. 94, this Court held that the federal statute permitting the Postmaster General to close the mails to persons engaged in obtaining money by false and fraudulent pretenses could not be construed to apply to any case in which there was a difference of medical opinion concerning the effectiveness of a particular treatment. The Court said that such an application of the statute would raise "some grave questions of constitutional law" (187 U. S. at 103).

A few years later, in *United States v. Johnson*, 221 U. S.

488, this Court came to a somewhat similar conclusion with respect to the Food and Drugs Act of June 30, 1906 (34 Stat. 768), which made it unlawful to misbrand products by means of "false or misleading" statements in the labeling. It held that the definition of misbranding contained in that Act did not apply to statements in labels concerning the effectiveness of a drug. One reason given for this conclusion was that it was considered unlikely that Congress would "distort the uses of its constitutional power to establishing criteria in regions where opinions are far apart" (221 U. S. at 498). Mr. Justice Hughes wrote a dissent, joined in by Mr. Justice Harlan and Mr. Justice Day, concluding that the Act did apply to statements dealing with effectiveness in cases where the product was "absolutely worthless and hence the label demonstrably false" (221 U. S. at 507), but adding (*id.*):

> I entirely agree that in any case brought under the act for misbranding,—by a false or misleading statement as to curative properties of an article,—it would be the duty of the court to direct an acquittal when it appeared that the statement concerned a matter of opinion.

Following the *Johnson* decision, Congress by Act of August 23, 1912 (37 Stat. 416), amended the Food and Drugs Act to provide that a drug product should be deemed misbranded if its label contained any "false and fraudulent" statement concerning the article's effectiveness. In *Seven Cases v. United States,* 239 U. S. 510, this Court in an opinion written by Mr. Justice Hughes held the statute constitutional, stating that Congress had "deliberately excluded the field where there are honest differences of opinion between schools and practitioners" (239 U. S. at 517).

By the Act of June 25, 1938 (52 Stat. 1040) Congress enacted the present Federal Food, Drug, and Cosmetic Act. It provides that a drug is misbranded "if its labeling

is false or misleading in any particular" (21 U. S. C. 352 (a)). The legislative history of this Act makes it abundantly clear that Congress, following the principle announced in the above cases, intended the present statute to have no application to instances in which there is a difference of medical opinion on the issue of effectiveness.[6] Therefore, the doctrine of those cases is equally applicable to the present statute.

In the case at bar, the Circuit Court of Appeals expressly recognized that it was going beyond that doctrine. It relied on what it called "Three Limitations to the McAnnulty

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[6] H. Rept. 2139, 75th Congress, 3d Session, accompanying Bill S. 5, which became the present law, states (p. 7):

"There are clear implications in cases arising under the old Food and Drugs Act and other laws that Congress may not, by a simple and unqualified prohibition against misleading representation, penalize the making of a representation of therapeutic effect regarding the truth of which expert opinion differs [citing cases].

"The reason for this limitation on the power of Congress is apparent. Whether the labeling of an article would be misleading and the product be thus misbranded would depend in a prosecution on whether the jury found it to be misleading.

"If Congress were to provide that a representation, about the correctness of which qualified opinion differed, would be misleading if the jury agreed with the experts holding one view but not misleading if the jury agreed with the experts holding the other view, it is apparent that the manufacturer would be unable to tell in advance whether his labeling violated the statute. There would therefore exist the kind of uncertainty which would invalidate the statute."

This report goes on to state that one of the important reasons for the inclusion of § 201 (n) of the Act (21 U. S. C. 321 (n)), which requires labeling "to reveal facts material in the light of" representations made, was that (p. 8):

> "If only a few experts regard a label statement of curative value as true but the great body of qualified experts in that particular field regard the statement as untrue, then there may be substantial ground for concluding that the curative claim is misleading unless it is qualified in such a way as to show the existence of conflicting opinion as to its truth."

The instant case was not, of course, tried or decided below on the issue of failure to reveal the existence of conflicting medical opinion—in which respect the labeling could easily be corrected—but on the flat issue of ineffectiveness. It is clear from this legislative history that the present Act was not intended to prohibit representations as to effectiveness supported by medical opinion.

Rule" (R. 1107). It held that the "McAnnulty case [has been] carefully limited in later decisions" (R. 1110)—all, as the opinion shows, decisions of lower federal courts. Those three limitations, according to the opinion, are (a) expert testimony as to tests made with the product, (b) testimony as to the consensus of medical opinion concerning the individual ingredients of the article, and (c) expert witnesses' personal opinions regarding its effectiveness, but based on no actual experience with the article (R. 1111-1118). The Circuit Court of Appeals apparently concluded that where the Government produced testimony of any one, or all, of these three kinds the question of effectiveness became a factual one for the jury, no matter how much honest, qualified medical opinion there might be in support of the product.[7]

We submit, first, that this well settled principle of the *McAnnulty* and other cases should not be fundamentally limited without consideration by this Court and, second, that the ruling of the Circuit Court of Appeals is plainly wrong. The rule of the *McAnnulty* and related cases is that, if there is an honest difference of medical opinion, the Court must direct a verdict against the Government. There is such an honest difference of opinion where there is qualified medical opinion in favor of the product as well

[7] The Circuit Court of Appeals attempted to bolster its decision by pointing to what it called factual evidence of untruths and half-truths in the labeling, which it said were alone enough to constitute misbranding (R. 1118-1122). In this connection, it referred to two testimonial letters which respondent had tried to discredit. It also referred to statements from reference books repeated in the labeling to identify the various ingredients, and to evidence introduced by respondent that the reference books contained certain unfavorable remarks which petitioner did not include in the labeling.

But that evidence is completely irrelevant to the issues on which the case was tried, and the verdicts of misbranding could not have been based on it. The sole issues in the case were whether the labeling represented the product as effective, and whether it is effective. These were the only issues raised in the libels (R. 4, 58, 80, 94). The district

as against it. The rule adopted by the Circuit Court of Appeals is that, if the Government introduces evidence based on clinical tests, then the case should go to the jury no matter what the nature or weight of the evidence in favor of the product.

Actually, the doctrine of the instant case would completely nullify the principle established by this Court's decisions. In any case where there is a difference of medical opinion, the Government undoubtedly can secure evidence based on such clinical tests as there were in this case. Under the instant doctrine, it would make no difference that equal or even stronger evidence based on similar clinical tests was introduced in support of the product. All such cases would go to the jury to weigh the conflicting evidence.

This result is fully exemplified in the case at bar. The record shows that all of respondent's expert testimony was

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court's pre-trial order expressly stated that these were the agreed issues (R. 22-23). And in its charge to the jury, the trial court time and again reiterated that these were the sole issues (R. 1057, 1060-1062, 1064-1065, 1067-1070, 1086, 1089-1090). The jury could not have reached its verdicts, therefore, without finding that the product is ineffective; in fact, the district court expressly so charged the jury (see, particularly, R. 1090). The accuracy of the testimonials and the completeness of the statements from the reference books have absolutely nothing to do with the question of whether the product is effective. Thus this evidence could not in any way have formed the basis of the verdicts.

This was expressly recognized by both courts below in their treatment of another aspect of the case. After entry of the judgments in the trial court, petitioner moved for release of the products under bond to permit amendment of the labeling to bring it into compliance with the law (R. 41, 72, 87, 101). Obviously, if the testimonials and statements from reference books constituted the misbranding, the labeling could easily be corrected to conform to the statutory requirements, as authorized by Section 304 (d) of the Act (21 U. S. C. 334 (d)). The district court denied the request, however, on the express ground that the jury had determined that the product is ineffective (R. 1096-1097). The Circuit Court of Appeals affirmed this ruling on precisely the same ground (R. 1133-1134). This conclusively demonstrates that both courts were of the view that the jury's verdicts were based solely on the finding that the product is ineffective.

actually *opinion* evidence (see pp. 5-6, *supra*. The court below in discussing this evidence time and again referred to it as *opinion* testimony (R. 1111, 1112, 1114, 1115, 1116, 1117, 1118). Yet it concluded that, because this testimony was based on clinical tests, it somehow became "factual" and presented an issue for the jury. Much of the testimony introduced by petitioner was also based on clinical tests (see pp. 3-4, *supra*). We think it is clear from the record that petitioner's medical evidence actually was stronger and better founded than respondent's. In any event, there certainly was a great amount of qualified expert testimony in support of the product. Despite this difference of medical opinion, the Circuit Court of Appeals held it a proper case for the jury. In practical effect, this is an overruling of the decisions of this Court.

2. The decision of the Circuit Court of Appeals determines an important question under the Federal Food, Drug, and Cosmetic Act which has not been, but should be, decided by this Court.

Basically, the question here concerns the application of the misbranding provisions of the Federal Food, Drug, and Cosmetic Act of 1938 to statements in labeling concerning the effectiveness of drug products. In *United States v. Johnson*, and *Seven Cases v. United States, supra,* this Court decided similar questions concerning the construction of the Food and Drugs Act of 1906, and the amendment of August 23, 1912. The Act has since been amended in 1938 to include labeling that is "false or misleading in any particular." This Court has never had occasion to consider the application of that provision to a statement concerning effectiveness supported by qualified medical opinion.

The rule of the above cases, as we understand them, is that labeling which represents a product as effective is not "false or misleading" as a matter of law, if there is qualified medical opinion in support of that view. As stated above (p. 9, fn. 6), the Act of 1938 was not intended to change this rule. The Circuit Court of Appeals has not suggested that the Act had any such effect. Nevertheless, the court below has, we think, applied the Act in a way entirely inconsistent with the rule under the earlier statutes.

That juries should decide between schools of medicine in the field of opinion, as the court below has held, is a doctrine which should not be entertained at least in the absence of clear and explicit congressional intent. Here Congress has stated the contrary and the court below has ignored that intent. We submit that this Court should decide the question of the proper application of the present Act in such a case as this.

3. The decision of the Circuit Court of Appeals raises serious questions as to the constitutionality of the Federal Food, Drug, and Cosmetic Act which should be decided by this Court.

The three decisions of this Court discussed above indicate very clearly that a statute proscribing labeling which reflects honest medical opinion concerning a drug's effectiveness would raise serious constitutional questions. The decision of the Circuit Court of Appeals applies the Act in just that way.

This Act is enforceable by criminal penalties (21 U. S. C. 333), as well as by libel and injunction proceedings. Under the decision below, all manufacturers and distributors of drug products concerning which there is any adverse medi-

cal opinion—which undoubtedly includes a great majority of such products—will be in constant danger of losing their personal liberty or private property on the basis of a jury's weighing of conflicting medical opinions. Such an application of the Act makes it so uncertain as to amount to a deprivation of due process of law in violation of the Fifth Amendment to the Constitution. *United States v. Cohen Grocery Co.*, 255 U. S. 81; *Connally v. General Const. Co.*, 269 U. S. 385; *Winters v. New York*, 333 U. S. 507, 517. Also, such an application does not permit the laying of a definite charge as required by the Sixth Amendment. If the statute is to be applied in this way, we submit that this Court should consider these important constitutional questions.

CONCLUSION

It is respectfully submitted that this petition for a writ of certiorari to the United States Circuit Court of Appeals for the Ninth Circuit should be granted.

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July 1948

APPENDIX

The pertinent provisions of the Federal Food, Drug, and Cosmetic Act (52 Stat. 1040, as amended, 21 U. S. C. 301 et seq.) are as follows:

Sec. 201. For the purposes of this Act—

• • • •

(g) The term "drug" means . . . (2) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals . . .

• • • •

(m) The term "labeling" means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.

(n) If an article is alleged to be misbranded because the labeling is misleading, then in determining whether the labeling is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling fails to reveal facts material in the light of such representations . . .

Sec. 301. The following acts and the causing thereof are hereby prohibited:

(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded.

• • • •

Sec. 304 (a) Any article of food, drug, device, or cosmetic that is adulterated or misbranded when introduced into or while in interstate commerce . . . shall be liable to be proceeded against while in interstate commerce, or

at any time thereafter, on libel of information and condemned in any district court of the United States within the jurisdiction of which the article is found . . .

(b) The article shall be liable to seizure by process pursuant to the libel, and the procedure in cases under this section shall conform, as nearly as may be, to the procedure in admiralty; except that on demand of either party any issue of fact joined in any such case shall be tried by jury . . .

SEC. 502. A drug or device shall be deemed to be misbranded—

(a) If its labeling is false or misleading in any particular.

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Research Laboratories, Inc.,
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United States of America

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

PETITIONER'S REPLY BRIEF

Argument

I.

In its brief in opposition to certiorari, respondent first contends (pp. 8-15) that the principle of *School of Magnetic Healing* v. *McAnnulty*, 187 U. S. 94, and related cases, has been limited by subsequent developments in medical science. Respondent's argument seems to run as follows: The *McAnnulty* rule must be limited to cases where efficacy is a matter of opinion, and not subject to factual proof. Evidence as to actual use, clinical observations, and the value of individual ingredients is factual data, not matter of opinion. Such evidence is available now whereas it was not at the time of the *McAnnulty* decision. Whenever the Gov-

ernment introduces that type of evidence, it is proper to submit the case to the jury, no matter what the nature of the evidence in support of the product, for then the question has become one of fact rather than one of opinion.

There are a number of answers to this contention:

(1) In the case at bar, no matter how respondent may attempt to characterize its evidence, the fact remains that its witnesses were asked for and gave only their *opinions* as to effectiveness (R. 225-226, 271-272, 276, 356-359, 404, 488, 560-562, 580-581). The Court of Appeals time and again referred to respondent's evidence as *opinion* testimony (R. 1111, 1112, 1114, 1115, 1116, 1117, 1118). The true fact is that respondent's witnesses testified as to their *opinions*, those opinions being based on actual use or information concerning ingredients.

(2) Petitioner introduced precisely the same kind of evidence in support of the product. Five eminently qualified physicians, all of whom had actually used the product for a number of years and three of whom had conducted extensive clinical tests with it, testified that it was effective (see summary of evidence at pp. 3-4 of Petition).*

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*In an effort to deprecate the weight of petitioner's testimony, respondent refers to the fact that some of it related to Sal-Trag, a concentrated form of Nue-Ovo, and states that it was "admitted" that Sal-Trag contains two ingredients not present in Nue-Ovo (Resp. Br. 6, n. 2). That statement apparently is inadvertent. In respondent's cross-examination of petitioner's witnesses, two vague references to a possible difference in ingredients were made (R. 792, 803). In both instances, the testimony was plainly inadmissible and inconclusive. And in each case a reading of the entire testimony of the witness demonstrates beyond doubt that he testified that the two products are the same. The uncontradicted evidence is that the products are identical, and both courts below were satisfied in that regard (see Petition 3, n. 2). In any event, the question here is not the weight of the evidence before the jury on the issue of effectiveness. The question is whether it was improper to submit that issue to the jury at all, since there was respectable medical opinion in support of the product. Furthermore, since the verdicts here were general and it cannot be determined on what theory the jury rested its decision, the propriety of permitting the jury to decide the question of effectiveness must be tested on the assumption that the jury found the products to be the same. *Williams* v. *North Carolina*, 317 U. S. 287, 291-292; and see discussion and cases cited at p. 7, *infra*.

(3) The type of evidence introduced by respondent is not the result of any scientific development since the *McAnnulty* decision. Respondent apparently draws the line between testimony based on actual experience with the product, and testimony based simply on knowledge of ingredients without actual experience. Respondent calls the former "factual data" and the latter "matter of opinion." But certainly doctors have always been able to testify from experience with a product. We agree that such testimony is better founded. Nevertheless, it is still opinion evidence, and there may be a wide divergence of opinion based on the same kind of experience, as there was in this case. In *United States* v. *Fifty-nine Tubes, More or Less, etc.*, 32 F. Supp. 958, 962 (S. D. N. Y.), the court held, in conflict with the decision below, that evidence based on laboratory experiments and clinical tests was opinion evidence and subject to the rule on difference of expert opinion.

(4) The decision below would not only limit the *McAnnulty* principle, as both the lower court (R. 1107, 1110) and respondent (Resp. Br. 11) admit, but it would completely nullify that principle. Whenever there is any difference of medical opinion concerning a product's effectiveness, the Government can secure this type of "factual data" based on actual use of the product. Under the decision below, the question of effectiveness would then go to the jury, no matter how much evidence there might be in favor of the product based on the same type of actual experience. Apparently respondent believes that the jury's qualifications to resolve the conflict between doctors improve if the doctors have had more experience with the product.

(5) Contrary to respondent's suggestion (Resp. Br. 12-15), there is nothing in *Seven Cases* v. *United States*, 239 U. S. 510, which even remotely supports such a result. In *McAnnulty*, and later in *United States* v. *Johnson*, 221 U. S. 488, the Court indicated that there probably would be a

difference of opinion concerning the efficacy of substantially all medical products or treatments, and therefore to avoid serious questions of constitutionality on grounds of uncertainty federal statutes should be construed not to apply to any such case. In *Seven Cases*, the Court recognized that there could be assertions as to efficacy which "are in no sense honest expressions of opinion but constitute absolute falsehoods and in the nature of the case can be deemed to have been made only with fraudulent purpose", and that Congress could properly prohibit such statements (239 U. S. at 518). But the Court carefully pointed out that "Congress deliberately excluded the field where there are honest differences of opinion between schools and practitioners" (239 U. S. at 517). Thus that decision simply means that Congress can proscribe statements concerning efficacy where there is no respectable medical opinion in support of the product. It in no way suggests that, where there is an honest difference of medical opinion, the case may be permitted to go to the jury for its conclusive determination even if the Government produces any evidence based on use of the product.

(6) Finally, even if it be assumed that there is rational basis for limiting or nullifying the doctrine of the *McAnnulty* and related decisions, we submit that it should not be done without review by this Court.

(7) As an adjunct of its argument concerning the *McAnnulty* rule, respondent suggests that Congress intended section 502(a) of the Federal Food, Drug, and Cosmetic Act (21 U. S. C. 352(a)) to change the rule so as to permit submission of the issue of effectiveness to the jury where there is evidence based on use of the product (Resp. Br. 11). In support of this view, respondent points to the House Report on the bill which became the present Act (Resp. Br. App. 18-20). But that Report proves just the contrary. It demonstrates that Congress considered that representations concerning curative effects fall into three

categories under the present law. *First,* where there is no qualified medical opinion in support of the representation, it is prohibited. *Second,* if only a few experts regard the representation as true but the great body of experts consider it untrue, the representation is prohibited under section 201(n) (21 U. S. C. 321(n)) unless it is qualified by a statement showing the existence of conflicting opinion (see the legislative history at note 6 on page 9 of the Petition). *Third,* where there is an honest difference of qualified medical opinion, the representation is not prohibited and the case may not be submitted to the jury to resolve the conflict of opinion. The House Report in no way suggests that a case involving conflicting opinions is to go to the jury if the Government introduces evidence concerning actual experience with the product.

Moreover, the desire of Congress is manifest in more than the House Report. Congress examined into the question repeatedly and rejected proposals to the contrary. The Tugwell Bill proposed that a drug be misbranded "if its labeling bears any representations * * * contrary to the *general agreement* of medical opinion" (S. 1944, 73d Congress, emphasis supplied; see also 79 Cong. Rec. 4749, 5024, and 5223). S. 2800 of the 73d Congress proposed to define misrepresentation as any statement "not supported by substantial medical opinion or by demonstrable scientific facts." S. 5 of the 74th Congress was much the same, but even then the committee report stated (Senate Report No. 646, 74th Congress):

> There exist now, and perhaps always will exist, differences of medical opinion with respect to the effect of therapeutic agents. Any attempt to regulate by law in those fields where honest differences of opinion exist between groups of qualified persons is contrary to public interest.

The House Report on this bill also explained this language as inapplicable to a representation "supported by any

sound evidence" (House Report No. 2755, 75th Congress). In the next Congress the language was revised to prohibit only a representation "not supported by persons who, by reason of scientific training and experience, are qualified as experts on the subject" and the Senate committee report thereon states (Senate Report No. 152, 75th Congress):

> The requirement that claims for drug products should be supported by medical opinion was deleted. Great difficulty always has been found in defining "medical opinion". * * * It would often be impossible to determine what the state of medical opinion is on controverted subjects.

S. 1077 of the 75th Congress was revised to provide expressly for disclosure in labeling of differences in opinion (see House Report No. 1613, 75th Congress), but in conference even this form of provision was dropped (House Report No. 1774, 75th Congress). Congress then adopted the present provision and explained it as set forth at note 6 on page 9 of the Petition here.

Again it is clear that, in any event, this Court should decide this new and important question concerning the application of the present Act.

II.

Respondent finally argues that, even if the evidence does show an honest difference of medical opinion and it was error to submit the question of effectiveness to the jury, the jury's verdict was justified under section 201(n) because the labeling did not disclose the existence of conflicting opinion (Resp. Br. 15-17). There are likewise several conclusive answers to this contention.

(1) In the first place, the record plainly shows that the case was tried and the jury's verdicts based solely on the issue of effectiveness, and not on the question of failure to disclose difference in opinion. The libels raised only the

issue of effectiveness (R. 4, 58, 80, 94), as respondent admits in its brief (p. 4). The pre-trial order stated this to be the issue (R. 22-23), as respondent likewise admits (Resp. Br. 4). The trial court charged the jury time and again that this was the only issue (see particularly R. 1090; see also R. 1057, 1060-1062, 1064-1065, 1067-1070, 1086, 1089). Petitioner's request for permission to relabel under 21 U. S. C. 334(d), which would clearly have been proper had the verdicts been based on failure to reveal conflicting opinion, was denied by the trial court on the express ground that "the jury had made a determination of the . . . ineffectiveness of this product" (R. 1096-1097). And the Circuit Court of Appeals affirmed that ruling on precisely the same ground (R. 1133-1134). In the face of all this, respondent points (Resp. Br. 16) to two sentences, taken from the context of a lengthy charge, in which the court referred broadly to section 201(n) without in any way relating that section to the question of failure to disclose difference of opinion.

(2) Even if it be assumed that the charge permitted the jury to find for respondent on alternative theories, the case must still be reversed for error in submitting the question of effectiveness to the jury. It is settled beyond question that, in the case of a general verdict after a charge involving alternative theories, the charge must be correct on each theory since it cannot be determined on which theory the jury rested its decision. *Stromberg* v. *California,* 283 U. S. 359, 368; *Williams* v. *North Carolina,* 317 U. S. 287, 291-292; *Cramer* v. *United States,* 325 U. S. 1, 36, n. 45; *Haupt* v. *United States,* 330 U. S. 631, 641, n. 1.

(3) In fact, respondent's contention in this respect argues more pointedly than anything we can say for both review and reversal in this case. Certainly the decision below cannot be sustained on both of the alternative theories, as it must be if respondent's interpretation of the charge is correct. If it be assumed that the jury's verdict was based

on a finding of ineffectiveness, the judgment was erroneous because it was improper to submit that question to the jury. If it be assumed that the jury's verdict rested on failure to disclose difference of medical opinion, the judgment was wrong in denying release of the product under bond for relabeling to comply with the law, as authorized by 21 U. S. C. 334(d). Any such defect could easily have been corrected simply by adding to the labeling a statement concerning the difference in expert opinion. Both courts below, however, denied petitioner's request in that respect on the ground that the jury had found the product to be ineffective (R. 1096-1097, 1133-1134).

Conclusion

For the foregoing reasons and those stated in the petition, it is respectfully submitted that the petition for a writ of certiorari to the United States Court of Appeals for the Ninth Circuit should be granted. The case is of importance in the administration of federal laws because, if difference of legitimate medical opinion may be treated as it was in the courts below, the reach of federal statutes relating to drugs, fair trade advertising, and the mails will be extended into a scientific field heretofore left free for professional development save in instances of real fraud. Particularly in view of the position expressed by Congress, such a change should certainly not be made except after consideration by this Court.

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September 1948.

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In the Supreme Court of the United States

OCTOBER TERM, 1948

No. 134

RESEARCH LABORATORIES, INC., PETITIONER

v.

UNITED STATES OF AMERICA

BRIEF FOR THE UNITED STATES IN OPPOSITION

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES CIRCUIT COURT OF APPEALS FOR THE NINTH CIRCUIT

OPINION BELOW

The opinion of the circuit court of appeals (R. 1102-1134) is reported in 167 F. 2d 410. The district court did not render an opinion.

JURISDICTION

The judgment of the circuit court of appeals was entered April 2, 1948 (R. 1135). The petition for a writ of certiorari was filed July 1, 1948. The jurisdiction of the court is invoked under Section 240(a) of the Judicial Code, as amended by the Act of February 13, 1925.

QUESTIONS PRESENTED

1. Whether, in a libel for condemnation action instituted against a drug under the Federal Food, Drug, and Cosmetic Act, evidence introduced by the Government with respect to actual use, clinical observations, and knowledge of value of constituent ingredients constitutes factual data which may be submitted to the jury to determine whether the therapeutic claims made in the labeling are false and misleading?

2. Whether petitioner's drug was shown to be misbranded under Section 502(a) of the Federal Food, Drug, and Cosmetic Act because its labeling failed to meet the requirement of Section 201(n) of the statute?

STATUTE INVOLVED

The Federal Food, Drug, and Cosmetic Act of June 25, 1938, c. 675, 52 Stat. 1040, 21 U.S.C. 301 *et seq.*, provides in part:

> SEC. 201. For the purposes of this Act—
>
> * * * * *
>
> (g) The term "drug" means . . . (2) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals . . .
>
> * * * * *
>
> (m) The term "labeling" means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.
>
> (n) If an article is alleged to be misbranded because the labeling is misleading, then in determining whether the labeling is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or

any combination thereof, but also the extent to which the labeling fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling relates under the conditions of use prescribed in the labeling thereof or under such conditions of use as are customary or usual.

* * * * *

SEC. 304. (a) Any article of food, drug, device, or cosmetic that is adulterated or misbranded when introduced into or while in interstate commerce * * * shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on libel of information and condemned in any district court of the United States within the jurisdiction of which the article is found . . .

(b) The article shall be liable to seizure by process pursuant to the libel, and the procedure in cases under this section shall conform, as nearly as may be, to the procedure in admiralty; except that on demand of either party any issue of fact joined in any such case shall be tried by jury . . .

* * * * *

SEC. 502. A drug or device shall be deemed to be misbranded—(a) If its labeling is false or misleading in any particular.

* * * * *

STATEMENT

Pursuant to Section 304(a) of the Federal Food, Drug, and Cosmetic Act, the United States filed four libels of information for the seizure and con-

demnation of various lots of a drug known as Nue-Ovo (R. 2, 56, 78, 92), which had been shipped in interstate commerce by petitioner. On stipulation of the parties, an order was entered consolidating all four causes for trial in the District Court of the United States for the Western District of Washington (R. 16-18).

Each of the libels charges that the drug, Nue-Ovo, is misbranded under Section 502(a) in that the statements in its labeling are false and misleading since they represent, suggest, and create the impression in the mind of the reader that the product is effective in the treatment of arthritis, rheumatism, neuritis, sciatica, and lumbago, whereas it is not effective in the treatment of those conditions.

As a result of pre-trial conferences, certain facts were agreed upon and incorporated into a pre-trial order (R. 18-29) which stated the issues to be as follows:

(1) Whether the product is ineffective in the treatment of arthritis, rheumatism, neuritis, sciatica, or lumbago (R. 23).

(2) Whether the labeling of the product suggests to the user that Nue-Ovo is effective in the treatment of arthritis, rheumatism, neuritis, sciatica, or lumbago (R. 23).

(3) Whether the product is misbranded by reason of the labeling (R. 23).

Evidence adduced by the Government demonstrated these facts:

(1) The labeling of the product suggests to the user that the product is effective in the treatment of

arthritis, rheumatism, neuritis, sciatica, and lumbago. This is admitted by petitioner (R. 1068, 1105).

(2) Most of the ingredients in Nue-Ovo have long been abandoned, or were never accepted, in medical practice because of their complete lack of therapeutic value (R. 190-264). It is a basic principle in pharmacology, a science that deals with the study of how drugs act (R. 191), that when two or more drugs are combined, the combination has no properties over and above the properties of the individual (R. 203). Those ingredients which do have a place in present-day medicine are present in Nue-Ovo in such minute quantities as to be of no value in the treatment of the disease conditions for which it is recommended (R. 204-228, 582).

(3) Clinical testing of Nue-Ovo upon patients under controlled conditions by experts in the treatment of arthritic and related conditions reveals that the product is wholly ineffective in the treatment of arthritis, rheumatism, neuritis, sciatica, and lumbago (R. 265-277, 319-359, 397-405). Almost parallel results were obtained when one group of patients was treated with a placebo (R. 355).[1] In one study, the group on Nue-Ovo showed no change, while the group on the placebo showed some improvement (R. 403).

Apart from these clinical observations, a specialist in therapeutics and other qualified physicians testified that from their knowledge of the ingredients of Nue-Ovo, and of the diseases for

---

[1] An inert substance made to look and taste like Nue-Ovo (R. 218, 219).

which it is offered, the product could not be effective in the treatment of any of those diseases (R. 223-231, 485-488, 558-563, 578-582).

(4) False statements and half truths had been utilized in the labeling and marketing of the product. The factual evidence to this effect presented by the Government demonstrated that petitioner had used false testimonials (R. 418-473, 662-674), deceptive methods in the use of the mails (R. 607-620, 898-908), and significant and deceptive omissions in the labeling of the product in respect to the analysis of its ingredients (R. 833-847).

Evidence adduced by petitioner was largely of the lay user type. Of 36 witnesses and one deposition, 30 were lay users. One physician, Dr. G. M. Taylor, testified that he had conducted clinical studies not with Nue-Ovo, the product under seizure, but with Sal-Trag,[2] another product manufactured by petitioner (R. 969-984). He concluded that Sal-Trag was effective in the treatment of arthritis, rheumatism, lumbago, and neuritis, but not for sciatica (R. 973-974). He could not account for the curative effects of Sal-Trag (R. 973). When pressed for an answer, he stated that the herb ingredients of Sal-Trag are not used in present-day medicine (R. 981-982).

Another physician called by the petitioner, Dr. Carl E. Lund, uses Sal-Trag in his practice in the

[2] The identity of Nue-Ovo with Sal-Trag became an issue in the case, since it was admitted that Sal-Trag contained two ingredients not present in Nue-Ovo, ephedrine and methenamine (R. 792, 803). The court charged the jury to consider evidence with respect to Sal-Trag only if it found that Sal-Trag and Nue-Ovo are one and the same except with respect to the difference they possess by reason of the higher degree of evaporation in Sal-Trag (R. 1065).

treatment of arthritis, rheumatism, neuritis, sciatica, and lumbago (R. 994). He could not explain the curative effects he stated had been obtained (R. 1012). He was not aware that the medical profession has abandoned use of the herb constituents in Nue-Ovo (R. 1016).

Still another physician who testified on behalf of petitioner, Dr. Ira A. Manville, conducted clinical investigations using both Nue-Ovo and Sal-Trag (R. 802). During part of the time when he conducted these studies, he was on the payroll of petitioner (R. 833). Some of the laboratory examinations connected with the studies were made on the premises of petitioner (R. 834). In computing the results of his studies, he admitted that he had thrown out the averages of one patient because they were extraordinarily high and would have thrown his ultimate averages out of line (R. 851).[3]

Petitioner's doctors admitted they would not use Sal-Trag or Nue-Ovo in the treatment of alcoholic neuritis (R. 753); pain in the back (lumbago) due to overwork (R. 753); sciatica (R. 974); acute sciatica (R. 754); acute traumatic arthritis (R. 755); syphilitic, gonorrheal, or other infectious arthritis (R. 756, 862); and neuritis resulting from a mechanical impairment (R. 980).

As a rebuttal witness, and without changing its position that clinical observations with respect to

[3] An accepted factor in arthritis, rheumatism, neuritis, sciatica, and lumbago is that they are characterized by intermittent periods when the pain leaves the patient entirely, and by periods when the pain is heightened (R. 220-221, 347-348). Dr. Manville admitted that the high improvement which he claimed he noted in his clinical studies might in many cases be attributable to a normal period of lessened pain following administration of the drug (R. 873; cf. R. 220-221).

Sal-Trag were not admissible, the Government called a physician, Dr. Harry H. Dutton, who testified that he had conducted clinical studies with Sal-Trag at the request of petitioner and had detected no improvement in any patient (R. 1031-1034).

At the close of the evidence, petitioner moved for a directed verdict (R. 1045) upon the ground that the evidence showed only a conflict of expert opinion as to the effectiveness of the drug (R. 1045-1046). This motion was denied (R. 1050). The jury found in each case that the product was misbranded as charged (R. 33, 69, 84, 98). On appeal, the circuit court of appeals affirmed the judgments (R. 1134).

ARGUMENT

1. Petitioner contends that it was improper to submit the case to the jury because there was an honest difference of medical opinion concerning the effectiveness of the product. In support of this contention, petitioner cites *American School of Magnetic Healing* v. *McAnnulty*, 187 U. S. 94, *United States* v. *Johnson*, 221 U. S. 488, and *Seven Cases of Eckman's Alterative* v. *United States*, 239 U. S. 510.

Petitioner urges that it is the rule of the *McAnnulty* case that if there is an honest difference of medical opinion the court must direct a verdict for the claimant. It is clear, however, that the *McAnnulty* rule is limited to those cases in which the question of the effectiveness of the treatment is a matter of opinion and is not resolved by demonstrable, definitive proof.

In seeking to ascertain whether Nue-Ovo has any efficacy in the treatment of the disease conditions

for which it is offered, the Government arranged to have a series of clinical studies conducted by eminently qualified physicians. Studies were conducted by Dr. John H. Wheeler, a practicing physician in Kansas City, Missouri, at the Out Patient Department of the University of Kansas (R. 265-272). Of six patients suffering from arthritis who used the medicine for a period of six weeks during 1944, three patients experienced no improvement, two were of the opinion that they were no worse, and one patient felt that he was definitely improved but complained of some new pain involving both knees (R. 269). In 1940, 23 patients suffering from arthritis were requested to use the preparation. Of these who used it for various intervals, two for two weeks and the rest for periods varying from two months to nine months, 18 experienced no improvement, the symptoms of three improved slightly, and two were of the opinion that they felt better. (R. 270, 271.)

Studies were carried on under carefully controlled conditions in the clinic of the University of California by Dr. Frances Baker, Director of the Department of Physical Medicine at the University, who had specialized in the study of arthritis (R. 319-357). The first test involved 20 patients. Fourteen were treated with Nue-Ovo and eight with a placebo (see *supra*, p. 5) for a period varying from 4 to 18 weeks. (R. 354.) One patient felt improved, one felt worse, two had such severe pain that a change in treatment was required, and the rest were unchanged. Almost a parallel result was obtained with the placebo (R. 355). Another test involved six patients over a period of two months. Five patients stated that they felt no better (R.

351, 352). Tests were also conducted by Dr. W. D. Edwards, a physician at a medical institution near Los Angeles. The patients suffering from arthritis disclosed no improvement, though apparent improvement was claimed by some of the group that were treated with the placebo (R. 397-404).

In addition to this testimony regarding actual clinical proof as to the inefficacy of Nue-Ovo, the Government presented the scientific pharmacological evidence referred to at page 5, *supra,* to establish that most of the ingredients in Nue-Ovo have no therapeutic value, (2) that a combination of such ingredients does not impart to the product any therapeutic properties which the individual ingredients do not have, and (3) that such ingredients of Nue-Ovo as are used in modern medicine are present in such minute quantity as to add no therapeutic value to it.

Physicians who had not made clinical studies as to the efficacy of Nue-Ovo, but who were shown to be qualified to express their opinion thereof without such studies, testified that the product would not be effective in the treatment of any of the diseases for which it was offered (R. 223-231, 486-488, 558-563, 578-582).

The Government's evidence, therefore, was by no means limited to the proffer of opinions as to the therapeutic value of the drug. It included factual data of the actual progressive results of elaborate and comprehensive tests of the drug made by eminently qualified persons on human beings suffering with the disease for which the drug was represented as a remedy. It also included evidence which established as a scientific fact that most of the ingredients in the product have no therapeutic value,

together with the consensus of medical opinion on this point (R. 1117).

Petitioner's contentions are premised upon the assumption that, as a matter of constitutional law, Congress may not permit a claim of effectiveness on behalf of a drug product to be found false or misleading by a jury when a difference of medical opinion exists. In the *McAnnulty* case, involving the issuance of a fraud order by the Postmaster General, this Court held that the claims of effectiveness made on behalf of the school could not be condemned as false, since there existed a difference of medical opinion and consequently there was no standard of fact which could be utilized to ascertain the truth or falsity of the representations. It is clear, however, that tremendous strides in science and medicine have been made since the *McAnnulty* decision, and that numerous questions with respect to which only opinions formerly existed have now been resolved by newly evolved scientific principles based on factual data. In any event, it is apparent that Congress so worded Section 502(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352), with the *McAnnulty* decision in mind, as to permit claims of effectiveness made on behalf of a drug to be found false or misleading where that issue can be demonstrated to a jury as a fact.[4] No better evidence as to the safety or effectiveness of the drug can be adduced than the actual results of the use of the prod-

[4] This is made clear in that portion of the legislative history quoted in the Appendix *infra*, pp. 18-20). Historical development in the judicial attitude toward products offered to the public for the treatment of disease is thoroughly analyzed in *United States* v. *7 Jugs* * * * *Dr. Salsbury's Rakos*, 53 F. Supp. 746 (D. Minn.).

uct by a patient under the direction of a qualified expert. As the judge who presided at the trial lucidly said, in denying petitioner's motion for a judgment notwithstanding the verdict (R. 1094):

> * * * it is not an expression of opinion when the Government experts say they conducted clinical tests in which unknown to the patients, they gave some of them, whether there were large numbers or small numbers, in the aggregate they were a very considerable number of persons in the various clinical tests, the remedy Nue-Ovo and others they gave a placebo, each of them thinking they were taking a remedy that was an effective treatment for arthritis, and each of these patients unquestionably afflicted with arthritis in its advanced stages. And in all instances the results of pain were almost identical, whether they took the colored water or whatever it was, or some bitters, or whether they took this remedy.
>
> Now that's a matter of fact. That isn't a matter of opinion, if the jury saw fit to believing.

Certainly it cannot be stated that the evidence of results obtained by competent scientific investigation cannot be used to ascertain the truth or falsity of therapeutic claims. This proposition was recognized by this Court in *Seven Cases of Eckman's Alterative* v. *United States,* 239 U. S. 510, 518, where it was pointed out, with respect to the Food and Drug Acts of 1906, that although Congress had deliberately excluded the field where there were honest differences of opinion, "Congress recognized that there was a wide field in which assertions as to curative effect are in no sense honest expressions of opinion but constitute absolute falsehoods * * *." In the present case, the sig-

nificant fact is that the Government introduced evidence designed to establish as a fact, upon the basis of actual use, clinical observations, and knowledge of the constituent ingredients of Nue-Ovo, that the product is not effective in the treatment of arthritis, rheumatism, neuritis, sciatica, and lumbago. Further, the consensus of medical opinion (as distinguished from the casual opinion of one or more doctors) as to the therapeutic value of a drug or medicinal ingredient is necessarily based upon the history of its actual use over such a period as to establish its characteristics as an accepted fact.

The *McAnnulty* case did not hold that, in any case where a difference of medical opinion is shown, the trial court must direct a verdict against the Government irrespective of other evidence in the case. As pointed out above, it was recognized in *Seven Cases of Eckman's Alterative* v. *United States, supra,* that there is a category of assertions as to curative or therapeutic effect which falls outside the realm of opinion and can be demonstrated by factual evidence as constituting absolute falsehoods. Where there is a standard of demonstrable fact by which a claim of effectiveness can be measured, the rationale of the *McAnnulty* opinion, that claims of effectiveness as to which there is a difference of medical opinion cannot be condemned as false since there is no standard by which to measure the falsity or truth of the claims, is not applicable. This was pointed out specifically in *United States* v. *7 Jugs * * * Dr. Salsbury's Rakos,* 53 Fed. Supp. 746 (D. Minn.), where the court declared (pp. 758, 759):

> If the evidence is such that it appears that the question of effectiveness has not tran-

> scended the realm of opinion into the realm of demonstrable fact, the court must hold as a matter of law that assertions of effectiveness are not false and refuse to submit the question to the jury. * * * But where the evidence indicates that there is a standard of demonstrable truth and fact by which the jury can measure the claims of effectiveness, the court should then submit the question to the jury under appropriate instructions. * * *
>
> * * * * * *
>
> * * * Certainly where factual proof is present which indicates the worthlessness of the remedies in question, mere injection of an alleged difference of opinion on the part of persons whom the jury might find were either ignorant or charlatans, could not operate to prevent the jury from deciding the question of effectiveness. Under the evidence in this case, the jury was entirely warranted in finding that the contrary expressions of opinion by the witnesses appearing for claimant were in direct oppositions to established scientific fact.

It is plain, therefore, that petitioner has failed to take into account that, as pointed out by this Court in the *Seven Cases of Eckman's Alterative* case, the rule of the *McAnnulty* case does not apply in a field in which statements as to curative properties are downright falsehoods and in no case expressions of judgment. In any case which involves the therapeutic value of a drug, the question will ordinarily arise whether its lack of effectiveness can be demonstrated as a fact or whether there exists merely a difference of opinion. The circuit court of appeals clearly recognized that this problem exists, in holding that the evidence submitted by the Government fell within the field of demon-

strable fact upon the basis of which it could be determined by the arbiter of the facts that the therapeutic claims made on behalf of petitioner's product were false and misleading.

2. Aside from the question as to whether the Government demonstrated by factual evidence that the therapeutic claims made on behalf of petitioner's product were false and misleading, the verdict of the jury is supported by undisputed evidence of misbranding under Section 201(n) of the Act, *supra,* pp. 2-3.

If, as petitioner asserts, an honest and bona fide difference of opinion exists among practitioners and experts as to whether its product is effective in the treatment of the diseases named in the labeling, then it is clear that labeling which represents the article as effective must disclose that a difference of opinion exists with respect thereto.[5] The legislative history of the Act discloses that, in the consideration of Section 201(n), Congress had particularly in mind those representations as to therapeutic effect regarding the truth of which expert opinions might differ. Contrary to the assertion in the petition (p. 9), it is abundantly clear that Congress specifically intended the section to cover such situations. As shown by H. Rep. 2139, 75th Congress, 3d Session, *infra,* pp. 18-20, accompanying S. 5 which later became the Federal Food, Drug, and Cosmetic Act of June 25, 1938, Congress was aware of the rule of the *McAnnulty* case, but at the same time realized that in the marketing of drugs it

[5] The printed and graphic matter representing the labeling in this case is found in the record at pages 7, 8, 8A, 60, 63, 64 and 65. No semblance of compliance with the requirements of Section 201(n) is demonstrated.

would be most undesirable to permit misleading claims to be made simply because a few so-called experts could invariably be found to support them.

We must disagree with the statement contained in the footnote on page 9 of the petition to the effect that this case was not tried and decided on the issue of failure to reveal the existence of overwhelming opinion contrary to petitioner's claim for his product. The trial court, in charging the jury, quoted Section 201(n) (R. 1058), and then gave the following instruction (R. 1058-1059):

> It is therefore for you to determine, after a careful examination of the Government's exhibits entitled Exhibits 1, 2, 3 and 4, and all of the other evidence introduced in this case and all of the facts and circumstances disclosed during the course of the trial, whether there was a misbranding by reason of any representation that might mislead an ordinarily intelligent person, whether such statements be direct assertions of fact or the logical inferences to be drawn from the facts contained in the statement. Then you will also note from the law that I have quoted to you, that as a test to be applied to ascertain if the labeling is misleading, you will take into account not only the representations made or suggested by the words "design," "device," or any other combination thereof, or any combination thereof, but you will also take into consideration the failure to reveal facts, if any, that would be material in the light of representations made with respect to the consequences which would result from the use of the article when it is used in the manner indicated.

Clearly, the failure of the labeling to disclose the large body of opinion contrary to the therapeutic

claims made in such labeling constitutes a misbranding in that it is a failure under Section 201(n) to reveal facts material in the light of such claims. Consequently, the jury's verdict was justified irrespective of the issue of the effectiveness of the product.

CONCLUSION

The case was correctly decided below, and it presents no conflict of decisions and does not go beyond the doctrine of the *McAnnulty* and *Seven Cases of Eckman's Alterative* cases. We respectfully submit, therefore, that the petition for a writ of certiorari should be denied.

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APPENDIX

H. Rep. 2139, 75th Congress, 3d Session, accompanying S. 5, which later became the Federal Food, Drug, and Cosmetic Act of 1938, contains the following in respect to section 201(n) (p. 7):

Section 502 defines misbranded drugs and devices. In its first paragraph it makes an extremely important contribution to existing law in defining a drug as misbranded if its labeling is false or misleading in any particular. The present law contains this provision with respect to representations concerning the identity, strength, quality, and purity of the drugs, but therapeutic claims are amenable to action only if they are false and fraudulent. The persuasive effect of a false label on the consumer's mind is the same whether the representations were made in good faith or not. It has been demonstrated that effective protection of the public from falsely labeled nostrums is in many cases impossible under this language. This provision differs from that of the Senate bill (sec. 17 (a)), in that it omits the explanatory sentence:

> Any representation concerning the effect of a drug or a device shall be deemed to be false and misleading under this paragraph if such representation is not supported by persons who, by reason of scientific training and experience, are qualified as experts on the subject to which such representation relates.

It was felt that if a nostrum maker were able to obtain two or more persons who could qualify as experts and would testify in support of the label claims, the Government's case would be lost despite the fact that every competent expert in the country would unqualifiedly declare the claims to be false. The committee therefore substituted for this provision section 201(n).

This section is also offered as a solution to a difficult legal problem. It is a well-known principle of

law that a statute providing punishment for the commission of an offense must describe the offense with a reasonable degree of certainty. There are clear implications in cases arising under the old Food and Drugs Act and other laws that Congress may not, by a simple and unqualified prohibition against misleading representation, penalize the making of a representation of therapeutic effect regarding the truth of which expert opinion differs (Seven Cases *v.* United States, 239 U. S. 510; United States *v.* Johnson, 221 U. S. 488; American School of Magnetic Healing *v.* McAnnulty, 187 U. S. 94).

The reason for this limitation on the power of Congress is apparent. Whether the labeling of an article would be misleading and the product be thus misbranded would depend in a prosecution on whether the jury found it to be misleading.

If the Congress were to provide that a representation, about the correctness of which qualified opinion differed, would be misleading if the jury agreed with the experts holding one view but not misleading if the jury agreed with the experts holding the other view, it is apparent that the manufacturer would be unable to tell in advance whether his labeling violated the statute. There would therefore exist the kind of uncertainty which would invalidate the statute. But it is undesirable to permit misleading claims to be made simply because a few experts can be found on the occasion of a trial to support them.

One of the important applications of section 201(n) relates to this problem. If only a few experts regard a label statement of curative value as true but the great body of qualified experts in that particular field regard the statement as untrue, then there may be substantial ground for concluding that the curative claim is misleading unless it is qualified in such a way as to show the existence of conflicting opinion as to its truth. Certainly a

consumer seeking a remedy for a disease condition has the right to know, when it is a fact, that the representations of curative value have only a narrow and limited support; and if the labeling fails to reveal that fact, which is a material fact in the light of the representations made, then the labeling may be regarded as misleading. However, the misleading character of the label may be corrected by an appropriate qualifying statement revealing this material fact.

In such circumstances, therefore, the manufacturer can easily ascertain by consulting qualified experts in the field whether there is a material weight of opinion contrary to claims he desires to make, and there would exist no uncertainty of the kind that would invalidate the statute.

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